

## 510(k) Summary of Safety and Effectiveness

Manufacture Name:	Halifax Biomedical Inc.
Contact Name:	Chad Munro, P.Eng, MASc (Biomed.)
Postal Address:	11493 Route 19 Mabou, Nova Scotia, Canada B0E 1X0
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Contact:	Chad Munro, P.Eng, MASc (Biomed.)
Title:	President
Date:	February 6, 2009

Device Proprietary Name:	Tantalum Bead Set
Device Common or Usual Name:	Radiographic Marker
Classification Name:	Marker, Radiographic, Implantable
Classification Code	NEU – Class II
Classification Panel	General & Plastic Surgery
Regulation Number	878.4300

### Predicate Device:

Substantial equivalence is claimed to the following device as related to intended use and design characteristics:

- Tantalum Beads, Biomet, Inc. K010348

### Description of the Device

The Tantalum Bead Set consists of 1mm spherical x-ray markers made of commercially pure, unalloyed tantalum. They are used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an x-ray. The beads are applied with a manual surgical instrument. The beads are provided non-sterile in a cartridge which includes 16 beads. The cartridge, manufactured from PEEK is designed to be used with the Halifax RSA Bead Inserter (Class 1 device) to allow surgeons to deploy the beads into the bone and tissue surrounding an orthopaedic implant. The inserter and cartridge containing the beads must be sterilized by the hospital prior to use.

*Halifax Biomedical Inc.  
Traditional 510(k)*

*Tantalum Bead Set  
K090581*

**Intended Use of the Device**

The Tantalum Bead Set is to be used with the Halifax RSA Bead Inserter. Tantalum beads are to be used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an x-ray system. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair and bone fracture fixation procedures.

Clinical use references for tantalum markers are provided in Appendix A.

**Substantial Equivalence**

The Tantalum Bead Set is equivalent to the Biomet Tantalum Bead product based on the intended use, design, technology, material composition and performance.

**Conclusion**

Based on the information provided in this 510(k) premarket notification, the Tantalum Bead Set is substantially equivalent in terms of safety and effectiveness to the predicate device identified above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Halifax Biomedical, Inc.  
% Canreg, Inc.  
Roshana Ahmed  
Regulatory Affairs Manager, Devices  
4 Innovation Drive  
Dundas, Ontario  
Canada L9H 7P3

AUG 21 2009

Re: K090581

Trade/Device Name: Tantalum Bead Set  
Regulation Number: 21 CFR 878.4300  
Regulation Name: Implantable clip  
Regulatory Class: Class II  
Product Code: NEU  
Dated: August 11, 2009  
Received: August 19, 2009

Dear Roshana Ahmed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

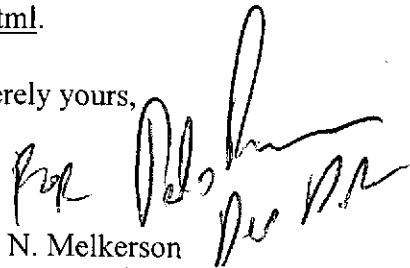
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Halifax Biomedical Inc..  
Traditional 510(k)

Tantalum Bead Set  
K090581

K090581

## Indications for Use

510(k) Number: K090581

Device Name: Tantalum Bead Set

Indication for Use: Tantalum bead implants are used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an x-ray system. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair and bone fracture fixation procedures.

Prescription Use  X   
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use        
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

  
Division Sign-Off

Office of Device Evaluation  
Evaluation and Safety

510(k) K090581